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Dr C M Longson
Director, Centre for Health Technology Evaluation
National Institute for Health and Clinical Excellence
Midcity Place
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14th August 2006

Dear Dr Longson

Re: Health Technology Appraisal for

alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women

and

Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women

I write in response to your letter of 31st July inviting comments on the additional analyses conducted for the above appraisals. Novartis wish to make a few minor comments which are detailed below.

Main Report, Modelling Methodology, page 5

sections 1 and 3
Both sections refer to there being an association between bisphosphonates and an increased risk of upper gastrointestinal (GI) problems. However, the Systematic Review (page 17) document more accurately notes that such GI problems are associated only with oral bisphosphonates. Therefore, in order to be both consistent and accurate, it should be made clear that statements on GI problems relate to oral bisphosphonates.

Section 4
This paragraph refers to compliance, yet elsewhere throughout the document the word "persistence" is used. Given the definition provided in the executive summary of the Systematic Review, it would be preferable to use consistent language.

Sensitivity Analyses, page 9

Sections 11, 12, 14 and 15 refer, again, to compliance but it is unclear whether, in fact, this is meant to mean persistence.

Table 11, page 37 and Table 19, page 41

The wording regarding teriparatide is rather confusing. Presumably, this is meant to imply that, in these cases, it may be appropriate to consider cost per QALY ratios of more than £20,000 rather than saying these are necessarily desirable.

If you have any questions, please do not hesitate to contact me.

Yours sincerely

Novartis Pharmaceuticals UK Ltd